10 Docket File

Lori Gelbort/Lymerix 1/31/01

I am grateful to have the opportunity to address this FDA Advisory Committee and devastated by the circumstances that bring me before you. My name is Lori Gelbort and since taking the Lymerix vaccine, my life has changed dramatically. Let me explain: My family and I live in Chicago. I have been married for 29 years; I have two children and am a social worker. Most importantly, until I took the Lymerix vaccine, I was a healthy and productive person.

My family spends summers in Southern Maine; an area with high Lyme incidence where we are surrounded by woods and grasses, viewing deer in the yard nightly. Already following recommended safety procedures, we decided to further protect our health by having the Lymerix vaccine. We received our vaccinations at the Travel Clinic of Northwestern Memorial Hospital, a major teaching hospital. Neither the staff nor the manufacturer's literature handed to us cautioned about the possibility of any long term ill effects. We were given no reason to believe that Lymerix warranted different consideration than any other immunization. My husband, fifteen year-old son, and I had the first two injections in the spring of 1999. On May 15, 2000, my husband and I received the third shot. The very next day I experienced body aches, and on May 17th, I awakened with severe pain in my hands. I was unable to bend my fingers closer than 90 degrees to my palms. I became incapable of performing activities such as basic personal care, brushing my teeth, and cutting food. Since early June, I have been constantly medicated, but I still have trouble with my hands. I continue to experience pain in other joints, such as my elbows, my knees, jaw, neck, and feet; and am usually fatigued. Previously, I was healthy and energetic; routinely taking only calcium and vitamins.

Only after experiencing this adverse reaction, did I learn that there had been concerns expressed about the safety of the vaccine; particularly related to the genotype HLA-DR4 for which I have since tested positive. This information most certainly would have enabled us to more realistically judge the relative risks and benefits of taking this

vaccine. If we had still believed the vaccine worthwhile for us, I could have had the option of genetic testing to avoid a problem rather than in response to one.

The lack of disclosure of this information had further ramifications for our family. After I became symptomatic, my son was still due for his third injection. To determine whether he should complete his series, I consulted with the chief of infectious diseases and travel medicine at Northwestern. Because the concerns about a possible genetic vulnerability apparently had not been shared with the wider medical community, this doctor believed my adverse reaction was an idiosyncratic response to the vaccine that would have no bearing on my son's health. I then consulted a physician more familiar with the vaccine, who advised against giving Lymerix to my son. Fortunately, Jason had not had the third dose. Imagine how awful it could have been had Jason followed my path.

It is apparent that Lymerix, an entirely optional measure intended as a preventative intervention, has harmed me physically, emotionally, financially, and has negatively impacted the life of my family. My daily functioning remains compromised. I lack the energy to maintain my former level of activity and commitments. My ability to work, volunteer in the community, and to share activities with my children has drastically diminished.

I was only trying to be diligent about my family's health and, as a result, I now have a health problem for which no effective solution may exist. I am faced with such diagnostic possibilities as "untreatable auto-immune disease arthritis" or "an activation of a previous exposure to the Lyme bacteria." There are few acknowledged experts regarding this reaction; and no widely accepted treatments.

It seems to me that when evaluating a vaccine, the possibility of adverse reactions of unknown duration, having no known cure, should receive greater weight than those potential reactions with well understood treatment protocols.

My husband and I have always had great confidence in the FDA's approval of medications and it's communication with the medical community. We expected that all information which physicians might reasonably need to make recommendations concerning our health would be made available to them. We were not informed that this very group expressed reservations which were not disclosed in the manufacturer's literature. We had no idea that there were unresolved safety issues requiring further study, and that by taking this vaccine our family would unwittingly become subjects of an ongoing drug trial. Doctors and their patients need to be given complete disclosure of the possible risks as well as the claimed benefits. Only then can they make prudent decisions together. We hope that others will have the benefit of all of the information necessary to make well-considered choices.

I appreciate this opportunity to share my experience with you. Thank you for your attention.